PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of:

Jones et al.

Serial No.: 10/644,256

Filed: August 20, 2003

For: EFFICIENT PRODUCTION OF IgA IN RECOMBINANT MAMMALIAN

CELLS

Confirmation No.: 6153

Examiner: To be assigned

Group Art Unit: 1632

Attorney Docket No.: 2578-6077US

CERTIFICATE OF MAILING

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August 12, 2005

Date

Betty Vowles

Name (Type/Print)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are <u>not</u> being submitted pursuant to M.P.E.P. 609 III A(2). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2) except as noted below.

U.S. Patent Documents

U.S. Patent No.	Publication Date	<u>Patentee</u>
US-4,703,008	10-27-1987	Lin
US- 4,835,260	05-30-1989	Shoemaker
US- 5,047,335	09-10-1991	Paulson et al.
US- 5,441,868	08-15-1995	Lin
US- 5,457,089	10-10-1995	Fibi et al.
US- 5,494,790	02-27-1996	Sasaki et al.
US- 5,767,078	06-16-1998	Johnson et al.
US- 5,773,569	06-30-1998	Wrighton et al.
US- 5,789,247	08-04-1998	Ballay et al.
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US- 2003/0087437 A1	05-08-2003	Asada et al.
US- 2003/0092160	05-15-2003	Bout et al.

Foreign Patent Documents

<u>Patentee</u>	Publication Date	Document No.
Amgen Inc.	02-23-1995	WO 95/05465
G.D. Searle & Co.	05-07-1998	WO 98/18926
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The University of British	10.00.1000	WO 00/44141
Columbia	10-08-1998	WO 98/44141

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WO 03/048348 A2	06-12-2003	Crucell Holland B.V.
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EP 0 411 678	02-06-1991	Genetics Institute, Inc.

Other Documents

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European Search Report 05 10 0732, April 7, 2005.

FALLAUX et al, "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," Human Gene Therapy, Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.

GRABENHORST et al., Construction of stable BHK-21 cells coexpressing human secretory glycoproteins and human Gal(beta-1-4)GlcNAc-R alpha-2,6-sialyltransferase alpha-2,6-Linked NeuAc is preferentially attached to the Gal(beta-1-4)GlcNAc(beta-1-2)Man(alpha-1-3)-branch of diantennary oligosaccharides from secreted recombinant beta-trace protein, Eur. J. Biochem, 1995, pp. 718-25, Vol. 232, No. 3, Berlin, Germany.

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MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, Biotechnol. Prog., 1995, pp. 348-51, Vol. 11, No. 3.

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In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.:

2578-6386US

Serial No.: Filing Date:

10/494,140 4/29/2004

Title:

METHODS AND MEANS FOR PRODUCING PROTEINS WITH

PREDETERMINED POST-TRANSLATIONAL

MODIFICATIONS

Attorney Docket No.:

2578-6471US 10/499,298

Serial No.: Filing Date:

10/25/2004

Title:

EFFICIENT PRODUCTION OF F(AB')2 FRAGMENTS IN

MAMMALIAN CELLS

Attorney Docket No.:

2578-6546US 10/512,589

Serial No.: Filing Date:

10/312,303

Title:

MEANS AND METHODS FOR THE PRODUCTION OF

ADENOVIRUS VECTORS

Attorney Docket No.:

2578-3982.3US

Serial No.:

10/783,510

Filing Date:

2/20/2004

Title:

MEANS AND METHODS FOR FIBROBLAST-LIKE OR

MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.:

2578-4038.3US

Serial No.:

10/790,562

Filing Date:

3/1/2004

Title:

RECOMBINANT PROTEIN PRODUCTION IN A HUMAN

CELL

Attorney Docket No.:

2578-4230.1US

Serial No.:

10/808,681 3/25/2004

Filing Date: Title:

MELANOMA ASSOCIATED PEPTIDE ANALOGUES AND

VACCINES AGAINST MELANOMA

Attorney Docket No.:

2578-3833.10US

Serial No.:

10/850,140

Filing Date:

5/20/2004

Title:

PACKAGING SYSTEMS FOR HUMAN RECOMBINANT

ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.:

2578-4070.2US

Serial No.:

10/951,102

Filing Date:

9/27/2004

Title:

SEROTYPES OF ADENOVIRUS AND USES THEREOF

Attorney Docket No.:

2578-4231.1US

Serial No.: Filing Date:

11/018,669 12/20/2004

Title:

GENE DELIVERY VECTORS PROVIDED WITH A TISSUE

TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR

ENDOTHELIAL CELLS

Attorney Docket No.:

2578-5447.1US

Serial No.:

11/039,767 1/18/2005

Filing Date: Title:

RECOMBINANT PRODUCTION OF MIXTURES OF

ANTIBODIES

Attorney Docket No.:

2578-6828US 11/070,890

Serial No.: Filing Date:

3/2/2005

Title:

RECOMBINANT PROTEIN PRODUCTION IN PERMANENT AMNIOCYTIC CELLS THAT COMPRISE NUCLEIC ACID

ENCODING ADENOVIRUS E1A AND E1B PROTEINS

Attorney Docket No.:

2578-5006.2US

Serial No.:

11/083,590

Filing Date:

3/18/2005

Title:

GENE DELIVERY VECTORS WITH CELL TYPE

SPECIFICITY FOR MESENCHYMAL STEM CELLS

Attorney Docket No.:

2578-3955.2US

Serial No.:

11/134,674

Filing Date:

5/19/2005

Title:

MEANS AND METHODS FOR NUCLEIC ACID DELIVERY

VEHICLE DESIGN AND NUCLEIC ACID TRANSFER

This Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,

Allen C. Turne

Registration No. 33,041 Attorney for Applicant(s) TRASKBRITT, P.C.

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Telephone: 801-532-1922

Date: August 12, 2005

ACT/bv/alb

Enclosures: Form PTO/SB/08

Document in ProLaw

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number 10/644,256

Filing Date August 20, 2003

First Named Inventor Jones et al.

Group Art Unit 1632

Examiner Name To be assigned

Sheet 1 of 3 Attorney Docket Number 2578-6077US

	۵.	Document Number	Publication Date	Name of Patentee or Applic	Name of Patentee or Applicant of		
Examiner Cite Initials * No.1		Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	:	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		US- 4,703,008	10-27-1987	Lin		Tigures report	
		US- 4,835,260	05-30-1989	Shoemaker		· · ·	
		US- 5,047,335	09-10-1991	Paulson et al.			
		US- 5,441,868	08-15-1995	Lin	T .		
		US- 5,457,089	10-10-1995	Fibi et al.	<u> </u>		
		US- 5,494,790	02-27-1996	Sasaki et al.	<u> </u>	* ****	
		US- 5,767,078	06-16-1998	Johnson et al.			
		US- 5,773,569	06-30-1998	Wrighton et al.			
		US- 5,789,247	08-04-1998	Ballay et al.			
		US- 5,830,851	11-03-1998	Wrighton et al.			
		US- 5,835,382	11-10-1998	Wilson et al.			
		US- 5,856,298	01-05-1999	Strickland			
		US- 6,033,908	03-01-2000	Bout et al.			
		US- 6,492,169 B1	12-10-2002	Vogels et al.			
		US- 6,558,948	05-06-2003	Kochanek et al.	***		
		US- 6,855,544	02-15-2005	Hateboer et al.		•	
		US- 2002/116723 A1	08-22-2002	Grigliatti et al.			
	US- 2003/0087437 A1		05-08-2003	Asada et al.			
	I	US- 2003/0092160	05-15-2003	Bout et al.			
		F	OREIGN PATE	NT DOCUMENTS			
Examiner	Cite	Foreign Patent Document		Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines,	
Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY			Where Relevant Passages or Relevant Figures Appear	Т6
		WO 95/05465	02-23-1995	Amgen Inc.			
		WO 98/18926	05-07-1998	G.D. Searle & Co.			
		WO 98/39411	09-11-1998	Baxter International Inc.			
		WO 98/44141	10-08-1998	The University of British Columbia			
		WO 99/05268	02-04-1999	Boehringer Mannheim GMBH			
		WO 00/61164	10-19-2000	Kenneth S. Warren Laboratories			
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	L	WO 03/038100 A1	05-08-2003	Crucell Holland B.V.			
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		WO 03/051927	06-26-2003	Crucell Holland B.			
		WO 2004/003176	01-08-2004	The Kenneth S. Warren Inst	itute, Inc.		
		WO 2004/099396	11-18-2004	Crucell Holland B.V	<i>I</i> .		
		EP 0 411 678	02-06-1991	Genetics Institute. In	ıc		
Examiner Signature				Date Considered			

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO				Complete if Known			
INFORMATION DISCLOSURE		Application Number	10/644,256				
				Filing Date	August 20, 2003		
STAT	NFORMATION DISCLOSURE STATEMENT BY APPLICANT	PPLICANT	First Named Inventor	Jones et al.			
				Group Art Unit	1632		
(use as many sheets as necessary)			necessary)	Examiner Name	To be assigned		
Sheet	2	of	3	Attorney Docket Number	2578-6077US		

	,	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BOUT et al., "Improved helper cells for RCA-free production of E1-deleted recombinant adenovirus vectors," Cancer Gene Therapy, 1996, pp. S24, Vol. 3, No. 6.	
		BOUT et al., "Production of RCA-free batches of E1-deleted recombinant adenoviral vectors on PER.C6," Nucleic Acids Symp. Ser. 1998, XP-002115716, pp. 35-36.	
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		CARROLL et al., Abstract, Differential Infection of Receptor-modified Host Cells by Receptor-Specific Influenza Viruses, Virus Research, Sep. 1985, pp. 165-79, Vol. 3, No. 2.	
		CRONAN, Abstract, Biotination of Proteins in-vivo a post-translational modification to label purify and study proteins, Journal of Biological Chemistry, June 25, 1990, pp. 10327-33, Vol. 265, No. 18.	
		European Search Report 05 10 0732, April 7, 2005.	
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		GRABENHORST et al., Construction of stable BHK-21 cells coexpressing human secretory glycoproteins and human Gal(beta-1-4)GlcNAc-R alpha-2,6-sialyltransferase alpha-2,6-Linked NeuAc is preferentially attached to the Gal(beta-1-4)GlcNAc(beta-1-2)Man(alpha-1-3)-branch of diantennary oligosaccharides from secreted recombinant beta-trace protein, Eur. J. Biochem, 1995, pp. 718-25, Vol. 232, No. 3, Berlin, Germany.	
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		HOLLISTER et al., Stable expression of mammalian beta1,4-galactosyltransferase extends the N-glycosylation pathway in insect cells, Glycobiology, 1998, pp. 473-80, Vol. 8, No. 5, IRL Press, United Kingdom.	
<u></u>		JENKINS et al., Getting the glycosylation right: Implications for the biotechnology industry, Nature Biotechnology, August 1996, pp. 975-81, Vol. 14, No. 8, Nature Publishing, US.	
		MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, Biotechnol. Prog., 1995, pp. 348-51, Vol. 11, No. 3.	

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Examiner		Date	
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO Complete if Known Application Number 10/644,256 INFORMATION DISCLOSURE Filing Date August 20, 2003 STATEMENT BY APPLICANT First Named Inventor Jones et al. Group Art Unit 1632 (use as many sheets as necessary) Examiner Name To be assigned Attorney Docket Number 2578-6077US

Sheet	3	of 3	Attorne	y Docket Number	2578-6077US		
·	,	OTHER PRIOR ART	NON PATEN	T LITERATUR	E DOCUMENTS		
Examiner Initials *	Cite No.1		l, symposium, catal		ele (when appropriate), title of the item (s), volume-issue number(s), publisher, ed.	T ²	
		PACITTI et al., Inhibition of Reovirus Type 3 Binding to Host Cells by Sialylated Glycoproteins Is Mediated through the Viral Attachment Protein, Journal of Virology, May 1987, pp. 1407-15, Vol. 61, No. 5, American Society for Microbiology.					
			PAU et al., Abstract, The human cell line PER.C6 provides a new manufacturing system for the production of influenza vaccines, Vaccine, Mar. 21, 2001, pp. 2716-21, Vol. 19, No. 17-19.				
		PAZUR et al., Abstract, Oligosaccharides as immunodeterminants of erythropoietin for two sets of anti-carbohydrate antibodies, Journal of Protein Chemistry, November 2000, pp. 631-35, Vol. 19, No. 8.					
		SCHIEDNER et al., Abstract, Effici new cell lines for adenoviral vector p			tes by E1 functions of Ad5: generation of 2116.		
		STOCKWELL et al., High-throughp Post-translational Modifications, Ch			ed Mammalian Cell-based Assays involving 3, Vol. 6, No. 2.		
		WEIKERT et al., Engineering Chinese hamster ovary cells to maximize sialic acid content of recombinant glycoproteins, Nature Biotechnology, November 1999, pp. 1116-21, Vol. 17, No. 11, Nature Pub. Co., New York, NY, US.					
		YU et al., "Enhanced c-erbB-2/neu of be suppressed by E1A," Cancer Res			elates with more severe malignancy that can		
					hamster ovary cells: functional consequences 8, pp. 441-52, Vol. 1425, No. 3, Elsevier		
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Examiner Signature				Date Considered			

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